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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,739	06/26/2006	Yoshiaki Hashimoto	KUZ0032US.NP	5791

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EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
12/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,739	HASHIMOTO ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The amendments filed on Aug. 19, 2009 have been entered.

Status of the Claims

Claims 1-7 and 11 are pending. Claim 1 has been amended; claims 8-10 are cancelled. Claims 1-7 and 11 are now under consideration. This Office Action is in response to the request for continued examination filed on Sep. 16, 2009.

OBJECTIONS/REJECTIONS MAINTAINED

The rejection of claims 1-6 and 11 under 35 U.S.C. 103(a) over TSURUDA and HONDA is maintained as discussed below.

The rejection of claims 1-6 and 11 under 35 U.S.C. 103(a) over TSURUDA and YASUKOCHI is maintained as discussed below.

The rejection of claims 1-4, 6, 7, and 11 under 35 U.S.C. 103(a) over '819 and TATEISHI is maintained as discussed below.

The rejection of claim 5 under 35 U.S.C. 103(a) over '819, TATEISHI, and HONDA is maintained as discussed below.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over TSURUDA (WO 01/68061; Published Sep. 20, 2001; Reference AC on IDS dated Aug. 3, 2006; U.S. Patent No. 6,924,410 is used herein as an English language translation) (hereinafter Tsuruda) in view of HONDA (U.S. 5,637,293; Issued Jun. 10, 1997; of record).

Since the WO publication is in Japanese, the U.S. patent to Tsuruda, which is the result of the national stage entry of the international application, is relied upon herein as an English language equivalent for all rejections based on WO 01/68061. Column and line numbers refer to the '410 patent.

1. Tsuruda discloses patches comprising a backing (i.e. a support) and an adhesive base (abstract; col., line 59 to col. 2, line 11). Tsuruda teaches that the adhesive base of the patches may preferably comprise a styrene-isoprene-styrene block copolymer (i.e. a macromolecule having a double bond at least in a principle chain thereof (col. 7, lines 7-14; col. 9, lines 4-5 and 17-26). The amount of the styrene-isoprene-styrene copolymer is preferably 10-50% by mass based on the total amount of the base (col. 7, lines 62-67; col. 8, lines 1-12). Tsuruda also teaches the inclusion of a non-steroidal anti-inflammatory, drug (NSAID), most preferably ketoprofen (col. 5, line 15), in the adhesive base, preferably in an amount of 0.1-30% by mass, more preferably 0.1-16% by mass (col. 2, lines 38-41; col. 5, lines 15-22; col. 7, lines 50-54; Formulations 1, 4, and 7) in the patches of their invention. Tsuruda teaches the use of preferred tackifiers

including hydrogenated rosin esters and terpene resins that may be used in combination in the adhesive base (col. 7, lines 21-24; col. 9, lines 27-45). Tsuruda teaches the use of tackifiers in an amount of 5-50%, more preferably 10-40% by mass relative to the total amount of the adhesive base (col. 9, lines 40-45), and teaches that the amount of tackifier can be used to regulate the viscosity and adhesive strength of the base (col. 9, lines 40-45). Furthermore, Tsuruda teaches the use of an ultraviolet (UV) screening agent(s) (e.g., UVA blockers such as benzotriazole derivatives (col. 2, lines 23-24); and UVB blockers such as benzophenone derivatives (col. 2, lines 24-29)), as a stabilizer, in preferable amounts of 0.01-20% by mass (abstract; col. 2, lines 12-33; col. 3, lines 41-49). Additionally, Tsuruda teaches the use of a variety of benzotriazole derivatives and other known organic UV screening agents such as cinnamic acid derivatives and amino acid-based compounds (col. 2, lines 20-29; col. 2, line 46 to col. 3, line 35).

2. Thus, the only difference between Tsuruda and the instant claims is that Tsuruda does not teach the UV blocker in the adhesive base. However, Tsuruda clearly establishes that incorporating the UV absorbent into the base was common practice in the art at the time of the invention. Tsuruda states, "the means for keeping the stability of a medicine in patches has generally been to incorporate an ultraviolet absorbent into the base" (col. 1, lines 39-41). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to incorporate the UV blocker in the adhesive base as was common in the art. Based on the disclosure of Tsuruda as a whole, the artisan would readily envision doing so, particularly in light of the related art.

3. For instance, Honda discloses topical preparations for drug delivery useful as, *inter alia*, cataplasms and plasters comprising UV blocking agents (abstract; col. 4, lines 29-32). The UV blocking agents of Honda are incorporated into the epidermal preparation and thus contact the skin (i.e. they are not in a backing). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to place the UV blocking agent(s) taught by Tsuruda in the adhesive base as was well-known in the art at the time of the invention. Doing so amounts to routine rearrangement of parts, to provide a predictable result. Furthermore, one would be motivated to include the UV blocking agent in the base as opposed to the backing to avoid the potential of unwanted removal of the UV blocker from the backing by normal wear and abrasion. Claims 1-4, 6, and 7 are rendered obvious over Tsuruda and Honda.

4. The UV blocking agents taught by Honda include both dibenzoylmethane derivatives (col. 2, line 60) and benzotriazole derivatives (col. 2, lines 61-62). In particular, Honda teaches that either 4-*tert*-butyl-4'-methoxydibenzoylmethane (col. 2, line 61) or 2-(2-hydroxy-5-methylphenyl)benzotriazole (i.e. 2-(2'-hydroxy-5'-methylphenyl)benzotriazole), which is taught as an acceptable benzotriazole derivative by Tsuruda (Example 1) are acceptable UV blockers in these formulations. Thus, it is clear from the teachings of Honda that 4-*tert*-butyl-4'-methoxydibenzoylmethane and 2-(2'-hydroxy-5'-methylphenyl)benzotriazole are expected to function in the same way.

5. Since Tsuruda teach the use of 2-(2'-hydroxy-5'-methylphenyl)benzotriazole as a UVA blocker, it would have been *prima facie* obvious to one of ordinary skill in the art at

the time of the invention to use 4-*tert*-butyl-4'-methoxydibenzoylmethane as a UV blocker in the patches of Tsuruda as both Tsuruda and Honda are directed to the same problem of blocking UV light in topical formulations. Because both compounds have the same function, the artisan would have had a high expectation of obtaining the predictable results of blocking UV light in the topical composition with the 4-*tert*-butyl-4'-methoxydibenzoylmethane. Claim 5 is rendered obvious over Tsuruda and Honda.

6. Tsuruda teaches embodiments wherein the patches further contain zinc oxide (Example 10, wherein Formulation 6 comprises a styrene-isoprene-styrene block copolymer and a NSAID), reading on instant claim 11. Thus, claim 11 is rendered obvious over Tsuruda and Honda.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that claim 9 was not included in the rejections over Tsuruda and Honda and Turuda and Yasukochi.

The omission of claim 9 from these rejections was an oversight, as it is noted that Tsuruda actually DOES teach the limitations of cancelled claims 8-10 (see col. 9, lines 27-45; see further discussion *supra*). As such, claim 9 should have been included in both of these rejections previously, and applicants should have been aware of Tsuruda's teachings. Thus, Tsuruda in combination with either of Honda or Yasukochi still reads on the amended claims.

Claims 1-7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruda in view of YASUKOCHI (U.S. 2005/0053646; Filed Jan. 24, 2003; of record).

7. The teachings of Tsuruda are presented *supra*. Tsuruda discloses that it was common practice to incorporate a UV absorbent into the base of a patch (col. 1, lines 39-41), but does not explicitly embody the use of UV blocking agents in the adhesive base *per se*.

8. Yasukochi discloses patches comprising pressure sensitive adhesives (abstract). Yasukochi teaches that the adhesives of these patches may contain a variety of additives including UV-absorbing agents (paragraph [0048]). Yasukochi teaches that these UV-absorbing agents can be used in amounts of 15 wt % or less, preferably 10 wt % or less relative to the total weight of the adhesive composition (paragraph [0048]).

9. It is noted that inclusion of the UV screening agent in either the backing or the adhesive base of the patch would have the same stabilizing effect on both the pharmaceutical compound and the rubber-system macromolecules in the adhesive base. Furthermore, adhesive bases comprising UV absorbing agents were known in the art at the time of the invention. Thus, placing the UV blocker in the adhesive base would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention based on the teachings of Tsuruda and Yasukochi. The artisan would have had a high expectation for obtaining the predictable result of preventing UV damage to the skin, pharmaceutical compound, and/or adhesive by including the UV-blocking

compound in the adhesive base in an amount of 10% or less. Claims 1-7 and 11 are rendered obvious over Tsuruda and Yasukochi.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that claim 9 was not included in the rejections over Tsuruda and Honda and Turuda and Yasukochi.

The omission of claim 9 from these rejections was an oversight, as it is noted that Tsuruda actually DOES teach the limitations of cancelled claims 8-10 (see col. 9, lines 27-45; see further discussion *supra*). As such, claim 9 should have been included in both of these rejections previously, and applicants should have been aware of Tsuruda's teachings. Thus, Tsuruda in combination with either of Honda or Yasukochi still reads on the amended claims.

Claims 1-4, 6, 7, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2003/0109819 (Filed Dec. 15, 2000) (hereinafter '819) in view of TATEISHI (WO 03/037393; Published Aug. 5, 2003; U.S. 2005/0042269 is used herein as an English language translation; of record).

Since the WO publication is in Japanese, the U.S. patent application to Tateishi, which is the result of the national stage entry of the international application, is relied upon herein as an English language equivalent for all rejections based on WO 03/037393. Paragraph numbers refer to the '393 application.

10. '819 discloses a patch comprising a styrene-isoprene-styrene block copolymer in an amount of 10-50% by mass, tackifier, and drug (abstract; paragraph [0015]). The patches comprise a support (paragraphs [0027]-[0029]; Examples 2 and 5) and an adhesive base (paragraphs [0008], [0010], and [0021]; claim 1). NSAIDs may be present in amounts from 0.001 to 30% by mass (paragraph [0026]) and ketoprofen is exemplified at a level of 4% (Example 2). '819 teaches blending a UV-ray absorbent such as benzophenone or benzotriazole derivatives, into the composition (i.e. the adhesive base) as necessary (paragraphs [0014] and [0031]). The tackifier is a rosin ester, hydrogenated rosin ester, maleic acid modified rosin ester, terpene, or petroleum resin and one or more of these may be blended, preferably in an amount from 10-40% by mass (paragraph [0024]). Thus, the only difference between '819 and instant claim 1 is that '819 does not disclose the *percentage* of UV absorbent useful in the invention.

11. It is noted that it is well within the purview of the ordinary artisan to optimize the concentration of a result-effective component (such as the UV absorbent of '819) with no more than routine experimentation. Nonetheless, Tateishi discloses patches having UV absorbers incorporated in the adhesive base layer of the patch and teaches that these components are suitably added in the range of not more than 10% wt % (paragraphs [0043] and [0044]). Thus, the artisan would have been guided by the art to use a UV absorber in this range. Claims 1-4, 6, and 7 are rendered obvious over '819 and Tateishi.

12. Both '819 (paragraph [0031]; Examples 5 and 6) and Tateishi (paragraph [0043]) teach the use of zinc oxide, rendering claim 11 obvious.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that they have demonstrated unexpected results for the claimed tackifier range. Applicants argue that the claimed range is critical because the prior art does not recognize the advantages of this range disclosed in the instant application (e.g. high skin permeability and prevention of crystallizaiton) (response, pgs. 6-9).

However, applicants' arguments regarding the alleged criticality of the claimed range are unpersuasive and applicants have not demonstrated the alleged criticality of the claimed range sufficiently to rebut the *prima facie* case of obviousness established by the Office. First, the prior art teaches the use of a combination of hydrogenated rosin ester and terpene resin in the instantly claimed % range. For example, '819 teaches that preferable tackifiers include, *inter alia*, hydrogenated rosin esters and terpene resins and teaches that one or more of these resins may be blended, preferably in an amount from 10-40% by mass (paragraph [0024]). Additionally, Tsuruda (WO 01/68061) teaches this limitation as well (see col. 9, lines 27-45 of 6,924,410). Both of these references teach that the content of the tackifier can be used to regulate the viscosity and adhesive strength of the base (see '819 paragraph [0024]; and col. 9, lines 40-45 of 6,924,410). Thus, the artisan would have expected to optimize this result-effective parameter.

Second, in response to applicants' argument that the prior art does not teach that the claimed range inhibits crystallization of the UV blocker and maintains a high skin penetrability, the fact that applicants have recognized another advantage which would

flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Third, the portion of the specifcation pointed to by applicants does not establish that the range of 10-20% tackifier is critical. Table 1 only provides data for three amounts of tackifier within the claimed range, 11, 14 and 18. At best this encompasses a range of 11-18 %, not 10-20%. No comparative data were presented to show that combinations of hydrogenated rosin ester and terpene resins in amounts above 20% or below 10% would NOT have the same effect as that instantly claimed (which, if presented, would further support the criticality of the range). Further, applicants own specification does not indicate that the range of 10-20% is CRITICAL; it is merely a preferred embodiment (paragraph [0047] of the pre-grant publication). In fact, paragraph [0047] of the pre-grant publication states that the amount of tackifier is preferably 3-50% mass % relative to the total amount of the base, more preferably 5 to 45 mass %, and yet more preferably 7 to 40 mass %, and the viscosity and the adhesive strength of the base are adjusted so as to be in the above-mentioned ranges. This is precisely what is taught by the prior art. Apparently all that applicants have done is optimize the amount of tackifier based on the teachings of the prior art. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Finally, no mention of the desired unexpected properties even appears in the

claims. In response to applicants' argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicants rely (i.e., prevention of crystallization and/or precipitation and maintaining high skin permeability for the NSAID) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants further attempt to show unobviousness by arguing that they have proceeded contrary to accepted wisdom in combining hydrogenated rosin ester and terpene resins. Applicants rely on an excerpt from the Adhesive Tape Manufacturer's Association and Handbook of Adhesion Editorial Committee, in support of this assertion (response, p. 11).

There are a number of flaws in applicants' assertion. First, the teachings of the prior art, discussed *supra*, clearly establish that it is accepted wisdom in the art to combine hydrogenated rosin ester and terpene resins as tackifiers in adhesive NSAID preparations. Thus, it is unknown how applicants believe they have acted contrary to accepted wisdom in the art. Applicants' assertion that an artisan would not have combined these resins because they would have expected any polar ingredients to precipitate is without merit. The prior art suggests otherwise. Also, applicants have not established that the NSAIDs recited in the instant claims would be expected to precipitate. Indeed, it is not clear that an artisan would even consider ketoprofen, for example, to be polar at all given ketoprofen's highly non-polar benzophenone core

structure. Applicants have provided no evidence to establish such a nexus. Again, it appears that all that applicants have done is optimize the amount of tackifier based on the teachings of the prior art (i.e. proceeding completely in line with conventional wisdom in the art). "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In total, applicants have not sufficiently distinguished the claimed invention from the prior art to overcome the rejections of record and have not sufficiently rebutted the *prima facie* case of obviousness established by the Office.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2003/0109819 (hereinafter '819; of record) in view of Tateishi as applied to claims 1-4, 6, 7, and 11 above, and further in view of Honda.

13. The teachings of '819 and Tateishi are presented *supra*. '819 teaches the use of 2-(2-hydroxy-5-methylphenyl) benzotriazole, but not the related methoxy derivative. However, the use of related benzotriazole derivatives would have been obvious to an ordinary artisan.

14. For example, Honda discloses the use of both 4-tert-butyl-4'-methoxydibenzoylmethane (instantly claimed) and benzotriazole derivatives such as 2-(2-hydroxy-5-methylphenyl)benzotriazole as taught by Tateishi. Thus, the art establishes these compounds as functional equivalents and their substitution for one another is *prima facie* obvious. Claim 5 is rendered obvious over '819, Tateishi, and Honda.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants arguments against the rejection of claim 5 are the same as those against the rejection of claims 1-4, 6, 7, and 11 over '819 in view of TATEISHI. The response to these arguments has been presented *supra*, and is incorporated herein.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claims 4 and 6 recite "derivatives".

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name,

or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office (PTO) Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.I "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106).

In paragraphs [0032] and [0034], applicants mention a very limited number of specific derivatives, but do not make it clear that the term "derivative" is intended to encompass only those compounds. No definition of the term "derivative" is provided. Additionally, applicants have failed to provide any further description of the various derivatives as recited in instant claims 4 and 6 that would provide adequate written description of the compounds encompassed by the claim. Adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties. Applicants provide no direction as to what subset of derivatives out of all possible derivatives that exist in the art would possess the required properties and be useful to use as a UV protectant. Furthermore, the structures of the particular derivatives disclosed in the specification are not representative of other species of derivatives, for example salts, polymers, degradation products, metabolites, etc.

encompassed by the genus. In the present case, other than the specific derivatives mentioned, the disclosure fails to describe the claimed compounds in a manner that complies with the written description requirement of 35 U.S.C. 112, 1st Paragraph.

Conclusion

Claims 1-7 and 11 are rejected. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin S Orwig/

/David J Blanchard/
Primary Examiner, Art Unit 1643